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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,905	01/18/2002	Y. Tom Tang	PF-0721 USN	1620

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,905	TANG ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *1,2,8-10,13-43,45-84 and 86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,11,12,44,85 and 87-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-93 are pending in the application.

[2] Applicant's amendment to the specification, filed July 07, 2004, is acknowledged.

Lack of Unity

[3] Applicants' election with traverse of Group XV, claims 3-7, 11-12, 43-55, 85, and 87-93, reciting a polynucleotide encoding SEQ ID NO:2, including SEQ ID NO:17, is acknowledged.

[4] Applicants traverse the lack of unity requirement asserting the search and examination of Groups II and XV is not unduly burdensome as the polynucleotide of Group XV encodes the polypeptide of SEQ ID NO:2. Applicants' argument is not found persuasive.

While publications disclosing polynucleotide sequences with defined open reading frames *may* disclose the corresponding polypeptide sequences, it is false to assume the only source of disclosure of a polypeptide is one in which the polynucleotide sequence is disclosed. Polypeptides can be purified from natural sources in the absence of polynucleotide information. Therefore, in order to search the claims of Groups II AND XV, the examiner must search not only for polynucleotide sequences, but also for corresponding polypeptide sequences as well as for isolated polypeptides which are inherently identical to the claimed polypeptide with a defined sequence. The search for inherently identical polypeptides is a text-based search, independent of a

polypeptide sequence search, and resulting publications must be assessed for their inherent applicability to the polypeptide claimed. Thus, a serious search burden would be required for the examiner to search not only the polynucleotide sequences, but also the polypeptide sequences as well as inherently identical polypeptides which is required by the claim language.

Applicants argue the unity of invention standard must be applied in national stage applications, citing sections of MPEP § 1800 in support of their statements, particularly Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT, which states:

> *Example 17*
> Claim 1: Protein X.
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants argue unity of invention exists between claims 1-2, 9, 16-18, 30-42, and 56-68 and claims 3-7, 11-12, 43-55, 85, and 87-93. Applicants' argument is not found persuasive.

In response to applicants' argument, it is noted that the unity of invention standard *was* applied in evaluating the claims for unity of invention and restriction practice according to 35 U.S.C. 121 and 372. MPEP § 1893.03(d) states, "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted". Also, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding

technical feature is a contribution over the prior art. As stated in the Office action mailed June 15, 2004, the inventions of Groups I-CCXXXIV do not relate to a single general inventive concept because the inventions do not share a same or corresponding special technical feature and/or the special technical feature is not a contribution over the prior art. See the previous Office action for detailed reasons in support thereof. Thus, in accordance with PCT Rule 13.2, Groups II and XV do not have unity of invention.

[5] The requirement is still deemed proper and is therefore made FINAL.

[6] Claims 1-2, 8-10, 13-43, 45-84, and 86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[7] Claims 3-7, 11-12, 44, 85, and 87-93 are being examined on the merits. Claims 3-7, 11-12, 85, and 87-93 are being examined only to the extent the claims read on the elected subject matter.

Priority

[8] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application 60/144,992, filed July 22, 1999, is acknowledged. The sequences of SEQ ID NO:2 and 17 of the instant application are disclosed in provisional application number 60/144,992 as SEQ ID NO:2 and 5, respectively. Applicant is granted the benefit of the earlier filing date of provisional application 60/144,992 to the extent this provisional application provides support for the claimed subject matter. Accordingly, the following rejection(s) have been made based on a priority date of July 22, 1999.

Specification/Informalities

[9] In view of the amendment to the specification, filed July 07, 2004, the objection to the specification as set forth at item [2] of the Office action mailed June 15, 2004 is withdrawn.

[10] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, page 15, lines 9 and 13; page 51, line 33; page 60, line 36) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

[11] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: -- Human Polynucleotide Encoding a Polypeptide Homologous to Fatty Acid Coenzyme A Ligase 5 --.

Oath/Declaration

[12] The amendment to the specification, filed July 07, 2004, indicates that the instant application claims domestic priority to provisional application 60/144,992. However, the declaration indicates that the instant application claims priority to two provisional

applications – 60/144,992 and 60/168,858. It is suggested that applicants correct this defect in the declaration.

Claim Objections

[13] Claims 3-7, 12, 85, and 87-93 are objected to as being dependent upon claims drawn to a non-elected invention. It is suggested that applicants amend the claims such that they no longer depend upon claims drawn to a non-elected invention. In the interest of advancing prosecution, claims 3-4 have been examined as reciting the limitations of claims 1-2, respectively.

[14] Claims 5 and 11 are objected to as reciting non-elected subject matter. It is suggested that applicants amend the claims such that they no longer recite non-elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[15] Claims 3-7, 11-12, 44, 85, and 87-93 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or well-established utility. The claims are drawn to isolated nucleic acids encoding SEQ ID NO:2 (referred to as "SYNT-2" throughout the specification), fragments and

variants thereof, a cell transformed with said nucleic acid and an array comprising said nucleic acid.

The specification discloses that a cDNA library was constructed from RNA isolated from uterine tissue and an open reading frame encoding SYNT-2 was identified (pp. 55-57 and 78 of the specification). Provisional application 60/144,992, to which the instant application claims domestic priority, discloses SYNT-2 has an undisclosed level of homology to rat acyl-CoA synthetase (Table 2). The specification of the instant application discloses that SYNT-2 has an undisclosed level of homology to human fatty acid coenzyme A ligase 5 (p. 71). The examiner's sequence search indicates that SYNT-2 has similarity to other fatty acid coenzyme A ligase enzymes. It is noted that the specification does not assert that SEQ ID NO:17 encodes a polypeptide having fatty acid coenzyme A ligase 5 activity. Also, the specification fails to provide an alignment with other fatty acid coenzyme A ligase 5 enzymes such that possible conservation between other fatty acid coenzyme A ligase 5 polypeptides can be determined in order that the examiner can make a determination of whether the encoded polypeptide would have catalytic activity, *e.g.,* alignment of other fatty acid coenzyme A ligase 5 enzymes identifying residues known to be involved in substrate binding and catalysis. Absent an assertion that SYNT-2 has fatty acid coenzyme A ligase 5 activity and evidence that SYNT-2 has enzymatic activity, it is unclear as to whether SYNT-2 has fatty acid coenzyme A ligase 5 biological activity. Even assuming *arguendo* the record indicated that SYNT-2 has fatty acid coenzyme A ligase 5 biological activity, the examiner knows of no well-established utility for a fatty acid coenzyme A ligase 5 polypeptide or a

nucleic acid encoding therefor. The specification asserts the claimed nucleic acid is useful in the diagnosis, treatment, and prevention of immune, neuronal, and reproductive disorders and cell proliferative disorders including cancer (p. 1, top). However, the specification fails to disclose any specific cell proliferative, immune, neuronal, and/or reproductive disorder(s) that can be diagnosed, treated, or prevented using the claimed polynucleotide. In the absence of such disclosure, one of skill in the art is left to determine which – if any - cell proliferative, immune, neuronal and/or reproductive disorder(s) can be diagnosed, treated, or prevented using the claimed polynucleotide and the specific conditions necessary for such. The specification further discloses the use of the claimed polynucleotides for protein expression and hybridization. However, these utilities are not specific as *any* polynucleotides have such use. Therefore, the asserted utilities are not specific to the claimed polynucleotide and are instead general utilities that would be applicable to the broad class of polynucleotides.

[16] Claims 3-7, 11-12, 44, 85, and 87-93 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[17] Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claim 3 (claims 6-7 dependent therefrom) is indefinite in the recitation of "biologically active." The specification discloses the meaning of this term as "having structural, regulatory, or biochemical functions of a naturally occurring molecule" (p. 12, lines 11-12). However, the scope of biological activities encompassed by this term is vague and it is unclear from this definition as to what functions of the encoded polypeptide of SEQ ID NO:2 applicants intend as the meaning of "biologically active." It is suggested that, for example, the term "biologically active" be replaced with a term that clearly defines applicants' intended biological function.

[b] Claims 3 (claims 6-7 dependent therefrom), 4-5, and 11 (claims 12, 85, and 87-93 dependent therefrom) are rejected as reciting an improper alternative expression. It is suggested that, where claims recite "selected from the group consisting of," "and" be inserted prior to the last recited member of the Markush group. See MPEP 2173.05(h).

[c] Claim 87 (claims 88-93 dependent therefrom) is indefinite in the recitation of "specifically hybridizable" as it is unclear how similar a nucleic acid must be to specifically hybridize with at least 30 contiguous nucleotides of the nucleic acid of claim 11. Further, this term is unclear absent a statement of the conditions under which specific hybridization is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[18] Claims 3, 6-7, 11-12, 85, and 87-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention.

Claim 3 (claims 6-7 dependent therefrom) is drawn to a genus of isolated polynucleotides encoding a polypeptide comprising a naturally occurring amino acid sequence that is at least 90% identical to SEQ ID NO:2 and biologically active and immunogenic fragments of a polypeptide having SEQ ID NO:2. Claim 11 is drawn to a genus of isolated polynucleotides comprising a naturally-occurring polynucleotide sequence having at least 90% identity to SEQ ID NO:17, a complement thereof, and RNA equivalents thereof. Claim 12 (claim 85 dependent therefrom) is drawn to a genus of isolated polynucleotides comprising at least 60 contiguous nucleotides of the polynucleotide of claim 11. Claim 87 (claims 90-93 dependent therefrom), and 88-89 are drawn to an array comprising a genus of nucleotide molecules comprising a first

oligonucleotide or polynucleotide sequence specifically hybridizable or completely complementary with at least 30 or 60 contiguous nucleotides of a sequence of claim 11.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of claimed polynucleotides, i.e., the polynucleotide of SEQ ID NO:17. The specification fails to describe any additional representative species of the claimed genus. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". In the instant case, the claimed genus of polynucleotides encompasses species that are widely variant in both structure and function, including

(but not limited to) genomic sequences, allelic variants, and nucleic acid variants encoding polypeptides having function other than the activity of SEQ ID NO:2, *e.g.*, non-functional polypeptides. As such, the disclosure of the single representative species of SEQ ID NO:17 is insufficient to be representative of the attributes and features of *all* species encompassed by the claimed genus of polynucleotides.

Regarding claims drawn to naturally-occurring sequences, it is noted that MPEP § 2163 states (citing *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021), "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials". In this case, the specification fails to provide those characteristics that distinguish those "naturally occurring" polynucleotides encompassed by the genus of the claims from those polynucleotides that meet the sequence identity limitation, but are not "naturally occurring".

Given the lack of description of a representative number of polynucleotides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[19] Even if applicant demonstrates a specific and substantial or well-established utility for a nucleic acid encoding SEQ ID NO:2, the following rejection still applies. Claims 3, 6-7, 11-12, 85, and 87-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding SEQ ID NO:2, does not reasonably provide enablement for all variants of SEQ ID

NO:17 and polynucleotides encoding polypeptides comprising variants and fragments of SEQ ID NO:2 as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass a vast number of polynucleotide variants, including polynucleotides encoding polypeptides that are non-functional or have function other than the polypeptide of SEQ ID NO:2. The broad scope of claimed polynucleotides is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. In this case the disclosure is limited to a polynucleotide encoding SEQ ID NO:2.

- The lack of guidance and working examples: The specification provides only a single working example of the claimed polynucleotides, *i.e.*, SEQ ID NO:17. This single working example fails to provide the necessary guidance for making and/or using the entire scope of claimed polynucleotides. The specification fails to provide guidance regarding those nucleotides of SEQ ID NO:17 or amino acids of SEQ ID NO:2 that may be altered by substitution, addition, insertion, and/or deletion with an expectation of maintaining the desired activity. Furthermore, the specification fails to provide guidance as to how to use those variant nucleic acids – both naturally and non-naturally occurring - that encode polypeptides having activities other than the desired activity, *e.g.*, nucleic acids encoding non-functional polypeptides or polypeptides having activity other than SEQ ID NO:2.

- The high degree of unpredictability in the art: The nucleotide sequence of an encoding nucleic acid determines the corresponding encoded protein's structural and functional properties. Predictability of which changes can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining an encoded polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art

would expect any tolerance to modification for a given protein to diminish with each further and additional modification, *e.g.*, multiple substitutions. In this case, the necessary guidance has not been provided in the specification as explained in detail above. Thus, a skilled artisan would recognize the high degree of unpredictability that the entire scope of polynucleotides would encode a polypeptide having the desired activity.

- The state of the prior art supports the high degree of unpredictability: The state of the art provides evidence for the high degree of unpredictability in altering a polynucleotide sequence with an expectation that the encoded polypeptide will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). The teachings of Branden et al. are exemplified by Witkowski et al. (*Biochemistry* 38:11643-11650) who teach that a single amino acid substitution results in conversion of the parent polypeptide's activity from a beta-ketoacyl synthase to a malonyl decarboxylase (see e.g., Table 1, page 11647). Thus, the prior art acknowledges the unpredictability of altering a protein-encoding sequence with an expectation of obtaining a protein having a desired function and

discloses that even a single substitution in a polypeptide's amino acid sequence may completely alter the function of a polypeptide.

- The amount of experimentation required is undue: While methods of generating variants and isolating homologs of a given polynucleotide are known in the art, *e.g.*, by mutagenesis and hybridization, it is not routine in the art to screen for *all* polynucleotides having a substantial number of substitutions or modifications and encoding polypeptides having *any* function, as encompassed by the instant claims. Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified

> or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
>
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[20] Claims 3, 6-7, 11-12, 85, and 87-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 7-9, and 23-24 of copending US Application 10/098,841 (the "'841 application"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 3, 6-7, 11-12, 85, and 87-90 of the instant application are generic to all that is recited in claims 1, 4, 7-9, 23-24 of the '841 application. In other words, claims 3, 6-7, 11-12, 85, and 87-90 are anticipated by claims 1, 4, 7-9, and 23-24 of the '841 application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

[21] Claims 85 and 87-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending US Application 09/974,298 (the "'298 application"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 85 and 87-90 of the instant application are generic to all that is recited in claim 3 of the '298 application. In other words, claims 85 and 87-90 are anticipated by claim 3 of the '298 application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

[22] Claims 3, 6-7, and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US Patent Application Publication 2003/0073129 A1). The claims are drawn (in relevant part) to an isolated nucleic acid encoding a polypeptide comprising variants and fragments of SEQ ID NO:2, a recombinant vector, a host cell, an isolated nucleic acid comprising variants of SEQ ID NO:17 and complements and fragments thereof. Baker et al. teach a nucleic acid, SEQ ID NO:85 (PRO1250), that is 98.3% identical to SEQ ID NO:17, encoding a polypeptide that is 99.92% identical to SEQ ID NO:2. Baker et al. teach their nucleic acid can be inserted into an expression vector and used to transform a host cell (pp. 208-210).

Conclusion

[23] Status of the claims:

- Claims 1-93 are pending.
- Claims 1-2, 8-10, 13-43, 45-84, and 86 are withdrawn from consideration.
- Claims 3-7, 11-12, 44, 85, and 87-93 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner

Art Unit 1652

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